

Remarks

Claims 1-19, 37, 61, 63, 65, 67, 101, 103, 104, 106, 108, 111, 127, 138, and 147-163 were pending, of which claims 1-19 and 147-163 were currently under consideration. By this Amendment claims 1, 19, and 154 are currently amended; claims 2-5, 147, 148, and previously withdrawn claims 37, 61, 63, 65, 67, 101, 103, 104, 106, 108, 111, 127, and 138 are canceled without prejudice or disclaimer; and no new claims are presented. Thus claims 1, 6-19, and 149-163 remain pending and are currently under examination. No new matter is introduced.

Applicants acknowledge that the Examiner expressly indicated that all previous rejections under 35 U.S.C. § 103 have been withdrawn.

Claims 1 and 19 are currently amended, *inter alia*, to specify that the claimed polymer or polypeptide is an isolated polymer or isolated polypeptide and composed entirely of identical repeating units. Support for these amendments may be found in the specification, for example, at page 22, lines 22-24 (isolated) and page 20, lines 8-13 (composed entirely of identical repeating units).

Claim 154 is currently amended to delete the phrase “and are not separated by any neutral amino acids.” This amendment is made solely for purposes of clarity and not to avoid prior art.

Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner indicated that claims 1-19 and 147-163 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Applicants respectfully disagree, and, for reasons set forth below, request the Examiner to reconsider and withdraw his rejection of claims 1-19 and 147-163 under 35 U.S.C. § 112, second paragraph.

The Examiner alleged that claims 1 and 19 are unclear as to whether or not repeating charge motifs are or are not the “repeating units” in view of dependent claims. As a preliminary matter, it is to be noted that claims 2-5, 147, and 148 are canceled by the current amendment, thus removing them from the rejection. In addition, claims 1 and 19 are currently amended to specify that the polymer of claim 1, and likewise the polypeptide of claim 19, is composed entirely of identical repeating units. It will therefore be evident that claims 1 and 19 as currently amended necessarily associate the repeating charge motif with the identical repeating unit. As was previously discussed in the amendment filed 30 July 2003, “repeating charge motif” and “repeating unit” are not necessarily synonymous terms, although in certain embodiments they may coincide. In the case of claims 1 and 19 as currently amended, “repeating charge motif” and “repeating unit” do coincide.

In view of the foregoing, Applicants assert that the terms “repeating charge motifs” and “repeating units” have definite meaning as provided by the specification and as used within the claims as currently amended. Therefore claims 1 and 19 are not unclear as to whether or not repeating charge motifs are or are not the “repeating units” in view of dependent claims.

The Examiner also indicated that the claim recitation “are separated by an intervening sequence of at least 32 Å” is unclear as to what subjects are separated thereof. Applicants respectfully disagree. Claims 1 and 19 are currently amended to specify that each repeating charge motif is composed of a positively charged free amino moiety and a negative charge. Even without this amended language, and certainly with it, Applicants submit that the claim language is clear on its face to mean the positively charged free amino moieties of the at least two repeating charge motifs are separated by an intervening sequence of at least 32 Å. In the words of the Examiner, this means that the repeating charge motifs are separated by at least this distance. The claim clearly specifies this distance is measured between a reference point residing within the charge motifs, namely, the positively charged free amino moieties. Accordingly, Applicants submit that, contrary to the Examiner’s assertion, the claim recitation “are separated by an intervening sequence of at least 32 Å” is not unclear as to what subjects are

separated thereof. Similarly, the Examiner's assertion (on page 4 of the Office Action) that claims 11, 12, and 13 are indefinite because of their use of different minimum distances (115 Å, 155 Å, and 200 Å, respectively, rather than 32 Å) is respectfully traversed.

The Examiner asserted that the recitation of "mixed polymer" in claim 6 renders that claim indefinite because only one polymer is recited in claim 1 (from which claim 6 depends) and because the specification insufficiently and unclearly defines the term "mixed polymer". Applicants respectfully disagree. As was previously pointed out in the Amendment filed 30 July 2003, the specification makes clear at page 19, line 25, that the term "mixed polymer" refers to a polymer that is heterogeneous in backbone composition. Thus, contrary to the Examiner's assertion, Applicants maintain that use of the term "mixed polymer" in claim 6 does not render that claim indefinite.

The Examiner asserted that claim 15 is unclear as to how native would differ from the recitation of "non-native polypeptide" differs from native thereof which the specification does not clearly define. Applicants respectfully submit it is not clear what the Examiner is saying, and therefore here reiterate the argument already made of record that the terms native and non-native are clear not only on their face but also as exemplified at page 7, lines 13-15, of the specification.

The Examiner asserted that with respect to claim 18 the recitation "positive to negative charge ratio of 1:1" is unclear whether or not the claimed polymer has no net charge because the ratio of positive to negative is 1:1, whether or not the said ratio regards overall positive to negative charges, whether or not the claimed polymer comprises [an] even number of repeating charge motifs because [an] odd number of repeating charge motifs would not result in the ratio 1:1 thereof. In response, Applicants respectfully submit that the recitation "positive to negative charge ratio of 1:1" in claim 18 is clear, particularly in view of the current amendments to claim 1 specifying that the polymer is completely made up of identical repeating units and that each repeating charge motif (each residing within an identical repeating unit) is composed of a positively charged free amino moiety and a negative charge. In particular, Applicants

respectfully submit that the Examiner has attempted to draw distinctions that, at least as applied to the claim as it depends from claim 1 as currently amended, are not meaningful. The claim says on its face that the polymer is a polypeptide having a positive to negative charge ratio of 1:1. While it is the case that the claimed polymer has no net charge because the ratio of positive to negative is 1:1, and while it is also the case that the ratio regards overall positive to negative charges, it is irrelevant whether or not the claimed polymer comprises an even number or an odd number of repeating charge motifs because in either case the repeating charge motifs would result in the ratio 1:1. Therefore Applicants respectfully submit, contrary to the Examiner's assertion, with respect to claim 18 the recitation "positive to negative charge ratio of 1:1" is not unclear.

In summary, for reasons provided above, Applicants respectfully request the Examiner to reconsider and withdraw his rejection of claims 1-19 and 147-163 under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 102

The Examiner indicated that claims 1-6, 14-16, 18-19, 147-148, 152-160, and 162-163 are rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Pat. No. 5,514,581 to Ferrari et al. For reasons set forth below, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 1-6, 14-16, 18-19, 147-148, 152-160, and 162-163 under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,514,581 to Ferrari et al.

As a preliminary matter, it is again to be noted that claims 2-5 and 147-148 are canceled by the present amendment and are therefore removed from the rejection. In addition, claims 1 and 19 are currently amended to specify that the polymer of claim 1, and likewise the polypeptide of claim 19, is composed entirely of identical repeating units. It will therefore be evident that claims 1 and 19 as currently amended cannot be anticipated by Ferrari et al. because the latter discloses only polypeptide compositions that are not composed entirely of identical

repeating units. For example, SEQ ID NO:102 of Ferrari et al., cited by the Examiner, contains one Arg-Gly-Asp tripeptide and one Arg-Cys-Asp tripeptide, but is not composed entirely of identical repeating units. Therefore Ferrari et al. does not anticipate the instantly claimed invention. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 1-6, 14-16, 18-19, 147-148, 152-160, and 162-163 under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,514,581 to Ferrari et al.

The Examiner rejected claims 1-6, 14-16, 18-19, 147-148, 152-154, 158-160, and 162-163 under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Pat. No. 5,196,510 to Rodwell et al. For reasons set forth below, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 1-6, 14-16, 18-19, 147-148, 152-154, 158-160, and 162-163 under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,196,510 to Rodwell et al.

As a preliminary matter, it is again to be noted that claims 2-5 and 147-148 are canceled by the present amendment and are therefore removed from the rejection. In addition, claims 1 and 19 are currently amended to specify that the polymer of claim 1, and likewise the polypeptide of claim 19, is composed entirely of identical repeating units, wherein the positively charged free amino moieties of the at least two repeating charge motifs are separated by an intervening sequence of at least 32 Å and wherein the intervening sequence is neutral. While Rodwell discloses polypeptides with as many as three repeating Arg-Gly-Asp (RGD) tripeptides, Rodwell et al. nevertheless does not disclose polypeptides composed entirely of identical repeating units wherein the positively charged free amino moieties of the at least two repeating charge motifs are separated by an intervening sequence of at least 32 Å wherein the intervening sequence is neutral. Rodwell discloses the following peptides, which contain identical repeats of PSYYRGDGA: PSYYRGDGAPSYYRGDGA and PSYYRGDGAPSYYRGDGA. In each case the intervening sequence between the positively charged amino moieties (R) includes the sequence GDGAPSYY. This intervening sequence, though 8 amino acids long (corresponding to 32 Å), includes the negatively charged amino acid D; therefore the

requirement that the intervening sequence is neutral is not met. Therefore Rodwell et al. does not anticipate the instantly claimed invention. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 1-6, 14-16, 18-19, 147-148, 152-154, 158-160, and 162-163 under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,196,510 to Rodwell et al.

The Examiner rejected claims 1-2, 5, 14-15, 18, 147, 158-159, and 162 under 35 U.S.C. § 102(e) as being allegedly anticipated by U.S. Pat. No. 6,447,765 to Horwitz as evidenced by the known fact disclosed in the publication Bazan JF (1992) *Science* 257:410-3 [sic]. For reasons set forth below, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 1-2, 5, 14-15, 18, 147, 158-159, and 162 under 35 U.S.C. § 102(e) as being allegedly anticipated by U.S. Pat. No. 6,447,765 to Horwitz as evidenced by the known fact disclosed in the publication Bazan JF (1992) *Science* 257:410-3 [sic].

As a preliminary matter, it is to be noted that claims 2, 5, and 147 are canceled by the present amendment and are therefore removed from the rejection. In addition, claims 1 and 19 are currently amended to specify that the polymer of claim 1, and likewise the polypeptide of claim 19, is composed entirely of identical repeating units. Horwitz teaches a pharmaceutical composition comprising IL-2, which Bazan discloses to include, for example, three E-L-K tripeptides distributed irregularly within its overall primary sequence of approximately 133 amino acids. It will therefore be evident that claims 1 and 19 as currently amended cannot be anticipated by Horwitz because the latter, like Ferrari et al. (*supra*), discloses only polypeptide compositions that are not composed entirely of identical repeating units. Therefore Horwitz does not anticipate the instantly claimed invention. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 1-2, 5, 14-15, 18, 147, 158-159, and 162 under 35 U.S.C. § 102(e) as being allegedly anticipated by U.S. Pat. No. 6,447,765 to Horwitz as evidenced by the known fact disclosed in the publication Bazan JF (1992) *Science* 257:410-3 [sic].

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In summary, for reasons provided above, Applicants respectfully request the Examiner to reconsider and withdraw his rejection of claims under 35 U.S.C. § 102.

Summary

Claim amendments and arguments are presented in response to rejections made under 35 U.S.C. § 112, paragraph 2, and 35 U.S.C. § 102. The Examiner is urged to withdraw all rejections.

Applicants believe the claims are in condition for allowance. A prompt and favorable action is earnestly solicited.

Respectfully submitted,
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